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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,744	03/22/2005	Alastair D. Wright	NGP0025	6959

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BAKER & DANIELS LLP
111 E. WAYNE STREET
SUITE 800
FORT WAYNE, IN 46802

EXAMINER

ANDERSON, MICHAEL J

ART UNIT	PAPER NUMBER
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3767

DATE MAILED: 11/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No. 10/528,744	Applicant(s) WRIGHT, ALASTAIR D.	
	Examiner Michael J. Anderson	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 March 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 March 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:.
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>03/22/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Priority

1. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed in parent Application No. UK 0222166.1, filed on 09/25/2002.

Specification

2. The incorporation of essential material in the specification by reference to an unpublished U.S. application, foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference (see specifications page 4, first paragraph and page 6, fourth paragraph; PCT Patent Application entitled "Prefilled Fluid Handling Device" having the same priority date, the entire disclosure of which is incorporated herein by this reference), if the material is relied upon to overcome any objection, rejection, or other requirement imposed by the Office. The amendment must be accompanied by a statement executed by the applicant, or a practitioner representing the applicant, stating that the material being inserted is the material previously incorporated by reference and that the amendment contains no new matter. 37 CFR 1.57(f).
3. The disclosure is objected to because of the following informalities: figure 2 does not have elements labeled 112, 116, 163 and 186. Appropriate correction is required.

Claim Objections

4. The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claim 1 has been renumbered 19 in claims 20-22, 28-33 and 35.

Examiner notes that applicant states in the Arguments section of the preliminary amendment filed on 03/22/2005 that "Original claims 1-18 were canceled and new claims 19-36 have been added to include the amended claims filed in the International application and as listed in the International Preliminary Examination Report". However, there are only 35 new claims in the preliminary amendment, as it seems that original claims 1 and 2 have been combined into new claim 19.

5. Claim 25 is objected to because of the following informalities: in line 2 "wit" should be "with". Appropriate correction is required.

6. Claims 26 and 27 are objected to because of the following informalities: in lines 1 "the or" need to be removed. Appropriate correction is required.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 19-21, 28-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Dysarz (US patent # 6 228 054 B1) (Dysarz). Reference to structural elements in Dysarz will be with respect to figures 1-2 and 7-9 unless otherwise stated.

9. With regard to claim 19, Dysarz discloses in figures 1-2 and 7-9, a syringe (2) having a barrel, a plunger (1) and a needle unit (3), a needle-mounting hub (11), a biasing element (13), a stop element (23 and figure 34, #62) a part for connecting the needle housing to the barrel (4) and a lip seal (23).

10. With regard to claim 20, Dysarz discloses in figures 1-2 and 7-9, a syringe (2) having a barrel, a plunger (1) and a needle unit (3), a needle-mounting hub (11), a biasing element (13), a stop element (23 and figure 34, #62) a part for connecting the needle housing to the barrel (4), and a lip seal (23) integral with a connecting part.

11. With regard to claim 21, Dysarz discloses as discussed for claim 19 above and further discloses a stop element (23 and figure 34, #62) arranged to snap engage with the housing to couple the hub to the housing and to retain the biasing element in a stored energy condition.

12. With regard to claim 28, Dysarz discloses as discussed for claim 19 above and further discloses a hollow plunger (1).

13. With regard to claim 29, Dysarz discloses as discussed for claim 19 above and further discloses a connection mechanism (4) that requires excess force to remove the housing from the barrel.

14. With regard to claim 30, Dysarz discloses as discussed for claim 19 above and further discloses a snap fit connection mechanism (4).

15. With regard to claim 31, Dysarz discloses as discussed for claim 19 above and further discloses a coiled spring (13).

16. With regard to claim 32, Dysarz discloses as discussed for claim 19 above and further discloses a needle mounting hub (11) and stop element (23 and figure 34, #62) that are disengageable with the plunger (1).

17. With regard to claim 33, Dysarz discloses as discussed for claim 19 above and further discloses a piston member (21) and a hollow rod (1).

18. With regard to claim 34, Dysarz discloses as discussed for claims 19 and 28 above and further discloses a portion, which is severable (21 and figure 8, #20).

19. With regard to claim 35, Dysarz discloses as discussed for claim 19 above and further discloses the stop element (23 and figure 34, #62) is of cylindrical configuration and comprises a forward portion within the housing and a rearward portion of tapering configuration.

20. Claims 22-27 are rejected under 35 U.S.C. 102(b) as being anticipated by McGary (US patent # 5,769,822) (McGary). Reference to structural elements in McGary will be with respect to figures 1-2 and 4 unless otherwise stated.

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21. With regard to claim 22, McGary discloses in figures 1-2 and 4, a syringe (10) having a barrel (100), a plunger (200) and a needle unit (300), a needle-mounting hub (30), a biasing element (30), a stop element (32 and 34) a part for connecting the needle housing (30) to the barrel (106) and a lip seal (600) as described for claim 19 and sheath (20) that contacts the stop element.

22. With regard to claim 23, McGary discloses as discussed for claim 22 above and further discloses the sheath (20) that contacts (21 and 32) the stop element (32 and 34) and can be used to apply axial force.

23. With regard to claim 24, McGary discloses as discussed for claim 22 above and further discloses the sheath (20) that contacts (21 and 32) the stop element (32 and 34) and can prevent release of the needle-mounting hub (30).

24. With regard to claim 25, McGary discloses as discussed for claim 22 above and further discloses the stop element (32 and 34) with one or more projections (32) that engage "with" the housing (30) and abut the sheath (20).

25. With regard to claim 26, McGary discloses as discussed for claim 25 above and further discloses the projections on the stop element (32) that engage with the rib or the like on the housing (32).

26. With regard to claim 27, McGary discloses as discussed for claim 25 above and further discloses the projections on the stop element (32) with inclined outer.

Conclusion

References considered pertinent to Applicants' disclosure are listed on form PTO-892. All references listed on form PTO-892 are cited in their entirety.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael J. Anderson whose telephone number is (571) 272-2764. The examiner can normally be reached on M-F 7:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin C. Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MJA
11/06/2006

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER

